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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,124	05/10/2007	Linda Greensmith	CytRx/012	1776

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PATENT DOCKETING 39/361
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EXAMINER	
STONE, CHRISTOPHER R	
ART UNIT	**PAPER NUMBER**
1614	

MAIL DATE	DELIVERY MODE
11/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,124	GREENSMITH ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER R. STONE	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/03/2007, 09/08/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III (a method of treatment, claims 6-11) in the reply filed on October 24, 2008 is acknowledged.

Applicant's election with traverse of (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride citrate and amyotrophic lateral sclerosis in the reply filed on October 24, 2008 is acknowledged. The traversal is on the ground(s) that the claims have a unifying special technical feature, i.e. the treatment of neurodegenerative disease comprising administering (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride. This is not found persuasive because as noted in the requirement for restriction, mailed September 24, 2008, (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride is known and therefore cannot constitute a special technical feature (see p. 2).

The requirement is still deemed proper and is therefore made FINAL.

The examination has been extended to include both (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride citrate and (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride.

Claims 6-11 are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of amyotrophic lateral sclerosis (ALS), does not reasonably provide enablement for the prevention of ALS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 6-11 are drawn to a method of treating or preventing ALS comprising administering (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride citrate or (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride. The prior art indicates that ALS is difficult to prevent. In fact while many neuroprotective agents have been evaluated in clinical trials, none has shown unequivocal success and none has been approved by regulatory agencies (Cheung et al, Neurology, Vol. 67, 2006, p. 1749, abstract). This indicated a tremendous art recognized unpredictability with regard to the prevention of ALS. Applicant has provided no working examples demonstrating the ability of the instantly claimed method to prevent ALS and no guidance to allow one of ordinary skill to practice the prevention of ALS using the instantly claimed method. The data on pages 9-14 of the instant specification, only demonstrates the ability of the instantly claimed method to treat the disease in a mouse ALS model (i.e. to improve muscle function, motor unit survival, life span, etc. in mice with genotypes associated with the disease). For these reasons, i.e. the tremendous lack of predictability in the art and absence of

working examples and guidance, it would take undue burden by one of ordinary skill in the art to practice the prevention of ALS using the instantly claimed method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Biro et al (WO 03/026653 A1).

Claims 6-11 are drawn to a method of treating ALS comprising administering (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride citrate or (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride to a patient.

Biro et al (WO 03/026653 A1) teaches the administration of R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride or its citric acid salt to a patient (abstract, p. 4, lines 11-15, claims 5 and 6). The current claim construction does not require that the patient have ALS and therefore does not distinguish the patient of the claims from "any patient". Furthermore, in order to prevent disease one must logically administer before disease and therefore Biro et al meets the limitation to any patient to prevent. Biro et al does not explicitly teach that this method treats ALS; however the instantly claimed active step of administering (+)-R-N-[2-hydroxy-3-(1-

piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride citrate or (+)-R-N-[2-hydroxy-3-(1-piperidinyl)-propoxy]-pyridine-1-oxide-3-carboximidoyl chloride to the instantly claimed population, a patient, is taught. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please reference MPEP §2112. Preamble language in claims of patents directed to administration of drugs are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims, see Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). In the instant case, it does not appear that the claim language or limitations result in a manipulative difference in the method steps or difference in the patient population when compared to the prior art disclosure.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER R. STONE whose telephone number is (571)270-3494. The examiner can normally be reached on Monday-Thursday, 7:30am-4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

17November2008
CRS

/Patricia A. Duffy/
Primary Examiner, Art Unit 1645